REMARKS

Claims 1-100 have been cancelled. Claims 101-110 have been added to more particularly and distinctly recite the subject matter of this invention. Support for the new claims may be found in the specification, as follows:

Claim 101. Specification: page 10, lines 17 - 24 and page 19, lines 5 – 8.

Claim 102. Specification: page 22, lines 19 – 25.

Claim 103. Specification: page 22, line 23 and page 25, line 3-4.

Claim 104. Specification: page 22, lines 26-28.

Claim 105. Specification: page 14, line 39 - page 15, line 1.

Claim 106. Specification: page 9, lines 1-2 and page 11, line 31 – page 12, line 4.

Claim 107. Specification: page 19, lines 5 – 8.

Claim 108. Specification: page 15, lines 3 – 5.

Claim 109. Specification: page 22, line 25.

Claim 110. Specification: page 22, line 23.

No new matter has been added through the addition of these new claims.

Rejection Under Hawkins, et al. (US 5625036)

The rejection under Hawkins,et al. is respectfully traversed. Hawkins teaches a prothrombin time reagent that utilizes much higher concentrations of tissue factor than the invention recited in the pending claims. As provided in Col. 3, lines 14-15 in Hawkins, et al., the concentration of tissue factor taught is from 20 to 40 ng/mL. In the present invention, the coagulation activator component is utilized at a lower concentration in an effective amount to trigger a thrombin formation but not to result in a complete fibrin polymerization of said blood

or plasma sample. Per the discussion in the Specification of the present invention, the PT reagents, such as that taught by Hawkins,et al., are based on the addition of potent activators of the coagulation process and thus are only abnormal when major defects are present. These assays are not designed to detect the composite effect of multiple minor alterations (see discussion at pages 5-6 of Specification). The prothrombin time assay is insensitive to many changes in the coagulation pathway and is incapable of detecting hypercoagulability. The reagent claimed in the recited kit of the present invention is a single formulation capable of assessment of hypercoagulability, hypocoagulability and normal samples. Hawkins, et al. does not provide a reagent with this versatility. It is therefore respectfully requested that the rejection under 102 (b) based on this reference be removed.

Rejection Under Smirnov, et al. (US 5472852)

The rejection under Smirnov, et al. is respectfully traversed. Smirnov, et al. teach an assay useful for detection of a selective protein C inhibition. This teaching is distinguishable from the presently recited kit that contains reagent that is capable of differentiating hypercoagulability and hypercoagulability in a single formulation because the coagulation activator component is utilized at a lower concentration in an effective amount to trigger a thrombin formation but not to result in a complete fibrin polymerization of said blood or plasma sample. Smirnov, et al. does not teach a reagent of this type, and therefore it is respectfully requested that the rejection under 102 (b) based on this reference be removed.

Rejection under Brucato, et al. (US 6100072)

The rejection under Brucato, et al. is respectfully traversed. Brucato teach prothrombin time reagent where certain ratios of tissue factor to lipids are discussed in relation to purified

recombinant rabbit tissue factor. There is no teaching of a coagulation activator present in the amount whereby an assessment of hyper, hypo and normal plasmas may be distinguished in a single formulation. The present invention provides a single formulation that detects the composite effect of multiple alterations in coagulation. By teaching a prothrombin time reagent, Brucato, et al. does not teach an assay for detecting hypercoagulability (see Specification discussion at pages 5 - 6 of present invention). It is therefore respectfully requested that the rejection under 102(e) based on this reference be removed.

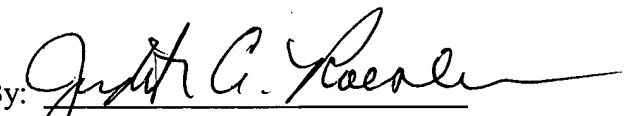
Rejections under 103 based on different combinations of art

New claims 101-110 recite kits that have a reagent capable of assessing hyper, hypo and normal coagulation in samples in a single formulation. For the reasons provided above, none of the primary references teach this recited invention. None of the secondary references teach a single reagent to assess hyper, hypo and normal coagulation in samples. Further, there is no suggestion that such a kit as presently claimed might be prepared. It is therefore respectfully requested that the rejections under 103 be removed because the combination of references does not render the presently claimed invention obvious.

Applicants respectfully submit this application is now in condition for examination on the merits and that all claimed subject matter is allowable. An early action to that end is earnestly solicited.

Should the Examiner have any questions, Applicants representative and the undersigned attorney may be contacted by telephone at (919) 620-2915.

Respectfully submitted,

By: 

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